MAR 2 4 2014

510(k) SUMMARY
K133593

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tandem Diabetes Care, Inc.
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Contact Person: John Sheridan, COO
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Date Prepared: November 22, 2013

Common or Usual Name

Insulin infusion pump

Classification Name

Infusion Pump per 21 CFR 880.5725

Predicate Devices

Tandem Diabetes Care, Inc. t:slim™ Insulin Delivery System (K111210)

Purpose of the Special 510(k) notice.

The purpose of this Special 510(k) is to provide an update on the changes made to the cartridge of the t:slim™ Insulin Delivery System. Specifically, the modifications include material/supplier changes to the insulin reservoir, luer, patient line tubing, UV adhesive and the outer pouch of the cartridge.

Intended Use

The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Device Description

The t:slim™ Insulin Delivery System is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. The scope of this Special 510(k) is limited to changes to the cartridge configuration of the t:slim System.

The t:slim System with the modified cartridge, like the predicate device, consists of the following components and accessories:

1. a software-controlled, programmable insulin infusion pump ("t:slim Pump" or "Pump"),
2. a dedicated, disposable 3mL (300 unit) insulin cartridge ("cartridge");
3. an UnoMedical Comfort™ Infusion Set (K051264), or an equivalently FDA cleared infusion set ("infusion set"); and
4. accessories, including a Becton Dickenson 3mL sterile syringe and 26 gauge sterile needle, or equivalently cleared syringe and needle, as well as an AC power supply with USB for charging the Pump's internal battery, cartridge Instructions for Use, and User's Guide.

The t:slim Pump is a battery operated infusion pump capable of both basal and bolus delivery of insulin. It utilizes a motor-driven mechanism to deliver insulin from within a disposable cartridge, through an infusion set, into a patient's subcutaneous tissue. As with current insulin infusion pumps on the U.S. market, the desired timing and quantity of the insulin delivery is programmed by the user (*i.e.*, the patient). The graphical user interface (GUI) of the t:slim Pump is a capacitive touch screen that displays information used to control the t:slim System. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge.

The t:slim cartridge is a single-use device, individually packaged and sealed, and provided sterile. The cartridge attaches to the t:slim Pump and is designed to hold up to 3 mL, or 300 units, of insulin. The delivery of insulin is accomplished through a micro-syringe within the head of the cartridge. The Pump has a pressure measurement sensor to estimate the volume of insulin in the insulin reservoir by measuring air pressure in the cartridge. This information is used to provide feedback to the software to determine the insulin volume, detect occlusions and cartridge removal.

Technological Characteristics

The t:slim Insulin Delivery System with modified cartridge has the same technological characteristics as the predicate device. The t:slim System consists of: (1) a software-controlled, programmable insulin infusion pump capable of both basal and bolus delivery of insulin ("t:slim Pump"); (2) a dedicated disposable 3mL (300 unit) insulin cartridge; (3) UnoMedical's Comfort™ Infusion Set (K051264), or an equivalently cleared set; and (4) additional device accessories including a sterile syringe and needle (for cartridge filling) and AC power supply with USB. The material changes were qualified per original device specifications and were shown to meet design requirements.

Performance Data

Verification and qualification testing was performed based on an evaluation of risks for the type of change involved. All the changes made to the cartridge were assessed to make sure all the risks were mitigated (e.g., the infusion flow accuracy, fill volume accuracy, leakage, bond strength and tubing integrity, shelf life, biocompatibility, insulin compatibility etc.,) and that no new risks were introduced as a result of these modifications. Material changes were supported by selection of medical grade materials, confirmation of biocompatibility testing per ISO 10993-1, repeated cytotoxicity testing, and leachables/extractables evaluation. Cartridge material changes were also evaluated by specific performance tests to confirm suitability of the material in the production

process through various installation, operational and performance qualification tests (IQ/OQ/PQ), and product inspection and release testing. Completed testing to support substantial equivalence determination include:

- Extractable and Leachables testing
- Chemical composition comparison (FTIR)
- Patient line bond strength testing
- Cartridge Pressure/leak testing
- Package seal integrity testing
- Production IQ/OQ/PQ
- Infusion flow accuracy
- Fill volume accuracy
- Biocompatibility tests
- Insulin Compatibility

Substantial Equivalence

The t:slim System with modified cartridge has the same intended use and indications for use, the same principles of operation, and same technological characteristics as the previously cleared predicate t:slim System. The purpose of this Special 510(k) is to update the materials used in the construction of the disposable cartridge and storage pouch. The verification and process qualification testing confirms that these changes meet the original product specifications. Thus, the proposed t:slim System is substantially equivalent to its predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

John Sheridan
Chief Operating Officer
Tandem Diabetes Care, Inc.
11045 Roselle Street, #200
San Diego, California 92121

Re: K133593
Trade/Device Name: t:slim™ Insulin Delivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LZG
Dated: February 27, 2014
Received: February 28, 2014

Dear Mr. Sheridan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133593

Device Name
t:slim™ Insulin Delivery System

Indications for Use *(Describe)*
The t:slim™ Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 12 years of age and greater.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2014.03.24 10:38:28 -04'00'

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